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PATENT
Customer No. 22,852
Attorney Docket No. 6530.0020-02

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES**

In re Application of:)
)
Brett Haarala et al.) Group Art Unit: 3763
)
Application No.: 09/690,473) Examiner: M. Hayes
)
Filed: October 18, 2000)
)
For: GUIDEWIRE COMPATIBLE PORT)
AND METHOD FOR INSERTING)
SAME)

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REPLY BRIEF UNDER 37 C.F.R. § 1.193(b)(1)

Pursuant to 37 C.F.R. § 1.193(b)(1), Appellants submit this Reply Brief to the Board of Patent Appeals and Interferences, in response to the Examiner's Answer mailed December 16, 2003.

Appellants acknowledge the Examiner's withdrawal of several grounds of rejection under 35 U.S.C. §§ 102(b) and 103(a) and the Examiner's indication that claims 113 and 114 have been allowed. The remaining issue in the present Appeal is whether the rejection of claims 60, 61, 63-68, 70-72, and 74-79 under 35 U.S.C. § 102(b) based on U.S. Patent No. 4,857,053 to Dalton ("Dalton") should be reversed.

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The following remarks address the Examiner's new comments appearing in the Examiner's Answer.

A. Contrary to the Examiner's Assertions, Dalton Does Not Disclose an Access Port Device Including a Septum That Forms an Exterior Surface Portion of the Access Port Device

Dalton discloses a matrix septum intended to be employed in a number of different arrangements. As discussed in more detail below, Dalton discloses embodiments of drug delivery devices including the matrix septum. In addition, Dalton also discloses that the matrix septum is contemplated for use in general closure embodiments, such as those involving the closure of containers containing sterile substances, biologically dangerous agents, pyrophoric chemicals, hygroscopic reagents, etc. Col. 3, lines 51-60. Accordingly, the general matrix septum illustrated in Figs. 1-3 of Dalton is disclosed as being capable of being implemented into a number of different arrangements in addition to drug delivery devices.

Focusing on the drug delivery device embodiments disclosed in Dalton, there is no disclosure in Dalton indicating that any of those drug delivery device embodiments would have a septum forming an exterior surface portion of the drug delivery device. As explained in the Appeal Brief, Dalton's drug delivery device shown in Figs. 4 and 5 (which is assembled in a process shown in Fig. 6) has a silicone layer 66 coating the matrix septum 20. Col. 6, lines 28-29. Similarly, the drug delivery devices described in Dalton's Examples 1 and 2 have an entire port potted in (i.e., covered with) a layer of silicone rubber. Col. 6, lines 65-66 and col. 7, lines 16-17. Regarding Dalton's drug delivery device of Example 3, Dalton describes that example as having a silicone gel sandwiched between elastomer sheets, but Dalton's brief description of that example

renders it somewhat unclear as to whether one of the elastomer sheets and/or a septum forms an exterior surface. Col. 7, lines 27-41. Consequently, Dalton lacks any explicit disclosure of a drug delivery device including a septum forming an exterior surface portion of the device.

In addition to lacking an explicit teaching, Appellants also submit that Dalton does not have any implicit disclosure of a septum that forms a portion of an exterior surface of a drug delivery device. In the Examiner's Answer at page 4, the Examiner cites Figs. 1 and 6 of Dalton after setting forth the Examiner's general allegation concerning an asserted disclosure of a "septum [that] forms a portion of the device's exterior." Appellants do not understand how the Examiner is apparently relying on Figs. 1 and 6 in support of his allegation. Appellants submit that neither one of those drawing figures provides any teaching of a drug delivery device that includes a septum forming an exterior surface of the device. With respect to Fig. 1 of Dalton, that drawing figure merely shows an embodiment of a matrix septum without showing that septum being associated with an implantable access site. Accordingly, Fig. 1 provides no support for the Examiner's allegation.

Similarly, Fig. 6 of Dalton provides no support for the Examiner's allegation about a septum forming a portion of an exterior surface. Fig. 6 illustrates a method of making the device of Figs. 4 and 5. Col. 3, lines 28-35 and col. 6, lines 20-21 and 34-37. Thus, rather than depicting an access port device, Fig. 6 merely depicts intermediate structural arrangements that are ultimately configured in the form shown in Figs. 4 and 5. As explained above, the subject matter of Figs. 4 and 5 does not teach a septum

forming an outer surface portion of a device because those figures show a silicone layer 66 coating the matrix septum 20.

In the Examiner's Answer at page 4, the Examiner notes that Dalton does mention that "in certain applications, . . . it may be desirable to embed the matrix septum, i.e., one or both sides, with a coating which smooths the surface." Col. 6, lines 10-14. Dalton also specifically mentions that a "silicone potting resin or curable coating" may be used to provide such embedding of the septum. Col. 6, lines 14-15. That disclosure at col. 6, lines 10-15 is completely consistent with Dalton's discussion of drug delivery devices which are potted with, or coated in, material. Col. 6, lines 28-29 and 65-66 and col. 7, lines 16-17. In view of the fact that Dalton discloses drug delivery devices having a potted or coated septum, it is clear that the "certain applications" mentioned in Dalton at col. 6, line 10 would include drug delivery devices. In other words, col. 6, lines 10-14 is completely consistent with Appellants' position that Dalton explicitly discloses drug delivery devices that do not have a septum forming an exterior surface, while lacking any explicit or implicit disclosure of a septum forming an exterior surface portion of an access port device.

Appellants note that Dalton does mention that an example of the "certain applications" mentioned at col. 6, line 10 includes "applications in which the turbulence or pattern of fluid flow across the matrix septum is critical."¹ Col. 6, lines 10-12. Such disclosure is not inconsistent with Appellants' position that the "certain applications"

¹ Contrary to the Examiner's allegation in the Examiner's Answer at page 5, Dalton does not disclose forming an additional layer around the septum "only when a particular concern about fluid flow is present." To the contrary, Dalton at col. 6, line 10 uses the abbreviation "e.g." (for example), not the abbreviation i.e. (that is), when referring to the applications involving turbulence or pattern of fluid flow. The use of the abbreviation "e.g." illustrates that the term "certain applications" is not limited to applications involving fluid flow issues.

mentioned at col. 6, line 10 includes drug delivery devices, especially considering the fact that Dalton discloses drug delivery devices having a coating or potting.

Since Dalton lacks any implicit or explicit disclosure of an access port device including a septum forming an exterior surface portion of the device, Appellants assume the Examiner is relying on an inherency allegation to reject the claims. If such an assumption is correct, the rejection is flawed even further because the Examiner has failed to satisfy the requirements for a proper inherency-based rejection, as dictated by legal precedent:

To establish inherency, the extrinsic evidence “must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill.”
“Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.”

In re Robertson, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999)(citations omitted).

Nothing provides any indication that Dalton's disclosed matrix septum would **necessarily** form a portion of an exterior of an access port device. Consequently, there is no basis for any form of inherency rejection of the claims.

For at least the reasons explained above, Dalton lacks any explicit, implicit, or inherent disclosure of an access port device including a septum forming an exterior surface portion of the device.

B. Appellants Disagree With the Examiner's Allegation That the Web 30 of Dalton is an Upper Body Part

Appellants disagree with the Examiner's allegation that the web 30 can be considered to be an upper body part. The web 30 is disclosed as being part of Dalton's

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matrix septum 20. Therefore, one of ordinary skill in the art would consider the web 30 as defining a part of a septum rather than defining an upper body part.

I. **Conclusion**

For at least the reasons given in the discussion above and in the Appeal Brief, the § 102(b) rejection applied to pending claims 60, 61, 63-68, 70-72, and 74-79 is improper. Accordingly, the Board of Patent Appeals and Interferences should reverse that rejection and permit allowance of all of the claims.

To the extent any extension of time is required to obtain entry of this Reply Brief, such extension is hereby respectfully requested. If there are any fees due which are not enclosed herewith, including any fees required for an extension of time, please charge such fees to our Deposit Account No. 06-0916.

Respectfully submitted,

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Dated: February 17, 2004

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